

### REMARKS

Claims 1-31 are pending. Withdrawn claims 1-24 have been canceled by amendment herein as shown above. Claim 26 has been amended for clarity. Applicants reserve the right to file one or more continuing applications directed to the subject matter of the canceled claims at any time during the pendency of this application. Thus, claims 25-30 are pending and stand rejected under 35 U.S.C. § 103.

The title has been amended as shown above to more accurately reflect the subject matter of the pending claims.

In view of the foregoing amendments and following remarks, Applicants request reconsideration of the application and withdrawal of the sole remaining rejection.

#### Request to Correct Inventorship Pursuant to 37 C.F.R. § 1.48(b)

This Request is filed in order to correct the inventorship of the above-identified patent application under 37 CFR §1.48(b) so as to eliminate the inventors who did not contribute to the currently pending claims.

The inventors of the currently pending claim are **John M. POLO, Catherine GREER** and **Thomas W. DUBENSKY Jr.** The following individuals, originally named as inventors, did not contribute to the subject matter of the pending claims:

Maria CALDERON-CACIA and Daniel DE LA VEGA Jr.

Thus, it is appropriate to remove these individual's names from the list of joint inventors on the application. A check to cover the \$130 fee is attached. Such action is respectfully solicited by way of this paper.

#### Rejections Under 35 U.S.C. § 103

All examined claims stand rejected as allegedly obvious over Dubensky. (Office Action, pages 2-3). In this regard, the Examiner requested that Applicants add the comments made by Dr. John Polo regarding Dubensky in the telephone interview conducted on May 15, 2003 to the written record. (Office Action, page 2).

Pursuant to the Examiner's request, Applicants detail herein the gist of Dr. Polo's statements. Dr. Polo is a co-inventor on both the pending application and cited Dubensky reference. During the telephone interview, he explained how Dubensky does not teach or

suggest the use of plaque assays for titering alphavirus replicon particles as set forth in the pending claims.

By way of background, Dr. Polo explained that those working in this field were concerned with measuring titer of two separate populations, namely (1) titer of alphavirus replicon particles and (2) titer of contaminating replication-competent (viable) alphavirus, if present. Dr. Polo attested to the fact that Dubensky, and indeed the art, as a whole, used plaque assays only in relation to population (2), that is for titering of contaminating replication-competent (viable) alphavirus, if present. He particularly noted that he and his co-inventors were referring to titer of replication-competent viable alphavirus using plaque assays at col. 19-20, bridging paragraph of Dubensky. (See, also, page 3 of the Office Action). Thus, plaque assays were not used to titer replicon particles as claimed and Dubensky doesn't teach or suggest that one could do so.

Indeed, Dr. Polo stated that he and the other inventors had not even contemplated using plaque assays to titer replicon particles. In this regard he noted that, at the time Dubensky was filed, titer measurements of replicon particle vector preparations were done using one of two assays -- transfer of expression assays and nucleic acid detection. Dr. Polo noted that the contribution he and the other inventors of Dubensky made with respect to measuring vector titer was in their disclosure of a novel assay method using a reporter cell line (*e.g.*,  $\beta$ -galactosidase). Throughout the interview, Dr. Polo stressed that that he and the other inventors listed on Dubensky reference had not even considered using plaque assay titering methods as claimed in the pending application. Rather, as detailed above, Dubensky mentions these assays solely in relation to determine the level of contaminating, viable virus.

In sum, Dr. Polo clarified that there was no motivation in Dubensky to use plaque assays as claimed and, further, no reasonable expectation from Dubensky, or in the field as a whole, such plaque assays would work. The various passages cited by the Office were not meant to be combined in the manner set forth in the Office Action and, accordingly, that no one would have been motivated to try such assays.

Since there is no basis in the reference or in the state of the art at the time of filing for making an obviousness rejection of any of the pending claims, Applicants respectfully submit that the rejection over Dubensky should be withdrawn.

**CONCLUSION**

In view of the foregoing, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further communications regarding this application to:

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Respectfully submitted,

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